

REMARKS

Claims 3-14 and 16-26 are pending in the application. Claims 3 and 4 are independent claims.

Claims 5-14 and 16-26 are rejected as being indefinite under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 101 as not being a proper process claim. Claims 5-14 and 16-26 are amended to replace the phrase "Use of a surface coating as claimed in" with the phrase "Method of". No new matter is added by virtue of the amendment. Withdrawal of the rejections in light of the amendments is respectfully requested.

The added drawings are objected to as failing to comply with 37 CFR 1.84(p)(5). The rejection proffers that the amendments to the specification have not been found. In that regard, the Examiner's attention is directed to page 2 of the Amendment and Reply filed with the Request for Continued Examination (RCE) filed on May 26, 2004. A copy of that page 2 is attached as Appendix A to this Reply. In light of the Amendment to the Specification, reconsideration of the objection, leading to its withdrawal is respectfully requested.

Claims 3-14 and 16-26 are rejected under 35 U.S.C. 103 as being unpatentable over USP 4759805 to Saruwatari et al. (col. 1 lines 43-51), USP 3730783 to Streel (col. 2 lines 31-50), USP 3255035 to Clough (col. 3, example 1), or AN 115:237352 in view of McGannon (The Making, Shaping and Treating of Steel, United States Steel). The rejection is respectfully traversed in light of the accompanying remarks.

The Examiner's statement that Saruwatari et al, Streel, Clough, and AN 115:237352 do not set forth to increase the surface tension of an object by the oxide coating and the coating substrate is an analytical test element is acknowledged. The rejection proffers that "McGannon in Figures 12-109 to 12-114 disclose(s) the surface tensions Vs. oxides in the same field of endeavor." It is submitted that McGannon is not analogous to the claimed invention, and thus does not qualify as prior art for an obviousness determination.

References within the statutory terms of 35 U.S.C. § 102 qualify as prior art for an obviousness determination only when analogous to the claimed invention. In re Clay, 966 F.2d 656, 658 (Fed. Cir. 1992). Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor,

regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. In re Deminski, 796 F.2d 436, 442 (Fed. Cir. 1986); see also In re Wood, 599 F.2d 1032, 1036 (CCPA 1979).

In re Bigio (No. 03-1358; August 24, 2004). As stated above, the rejection proffers that McGannon is in the same field of endeavor as the claimed invention. The proffer is traversed because the rejection did not follow the test for analogous art set out by the Federal Circuit, and as such has inappropriately expended the field of endeavor of the claimed subject matter.

This test for analogous art requires the PTO to determine the appropriate field of endeavor by reference to explanations of the invention's subject matter in the patent application, including the embodiments, function, and structure of the claimed invention. See Wood, 599 F.2d at 1036 (confining the field of endeavor to the scope explicitly specified in the background of the invention); see also Deminski, 796 F.2d at 442 (determining that the cited references were within the same field of endeavor where they "have essentially the same function and structure").

In re Bigio (No. 03-1358; August 24, 2004). In determining the appropriate field of endeavor, the rejection has failed to reference the subject matter of the patent application. Explanations of the invention's subject matter in the patent application, include at least the following:

1. Embodiments
Example 1, page 14-17, Comparisons of the filling times of a test capillary
2. Function
 - a. Background and Summary of the Invention
 - i. single-use articles used especially in medical diagnostics or environmental analysis – page 2 lines 3-4;
 - ii. for the hydrophilic modification of plastic surfaces whether of foils or formed pieces – page 3 lines 7-8
 - iii. which is why it does not appear to be suitable for modifying mass-produced plastic articles – page 4 lines 5-6

- iv. Moreover it should be possible to carry out the coating in a simple and reliable manner in order to be suitable for the modification of mass-produced articles – page 4 lines 11-14

b. Detailed Description of the Invention

- i. Aqueous samples also including biological samples like blood, urine, saliva, sweat and samples derived therefrom such as plasma and serum spread well on such surfaces. Such surfaces are characterized among others in that a boundary surface of a water drop forms an acute rim or contact angle on them – page 5 lines 10-15
- ii. The rim angle which is a result of the surface tensions of the test liquid and of the surface to be examined in a measure of the hydrophilicity of a surface – page 5 lines 21-23.
- iii. Surface coatings are particularly preferably used according to the invention in analytical test elements to increase the hydrophilicity - page 11 lines 1-3.
- iv. Surfaces that have been made hydrophilic are especially essential for capillary gap test elements – page 11 lines 16-17.
- v. Consequently it is necessary to endow the plastics used as a construction material for test elements with capillary active channels with hydrophilic properties i.e. to hydrophilize them – page 12 lines 13-16.

3. Structure

- a. The invention concerns an analytical test element or a test strip in which the sample liquid is transported from a sample application site to a determination site – page 11 lines 3-6.
- b. In this connection it is important that the analytical test element has at least one surface which is composed of at least one element that can be oxidized with water or an alloy that can be oxidized with water which has been treated by the action of boiling water or water vapour. The

materials described above come into consideration as elements and alloys – page 11 lines 8-15.

- c. Capillary gap test elements are test elements in which the sample liquid is moved in a transport channel (capillary channel, capillary gap) from a sample applications site to a distant sample detection site with the aid of capillary forces in order to undergo a detection reaction at this site – page 11 lines 17-23.
- d. Therefore in analytical test elements with capillary gaps at least one, but preferably two and especially preferably two opposing surfaces which form the inner surface of the channel capable of capillary liquid transport are preferably hydrophilized – page 12 lines 17-21.

It is respectfully submitted that the above explanations of the subject matter in the patent application must necessarily be considered in determining the appropriate field of endeavor of the claimed invention. The application provides no basis for expanding the scope of the field of endeavor as proffered by the rejection.

[S]ubstantial evidence must support the PTO's factual assessment of the field of endeavor. Gartside, 203 F.3d at 1315. In other words, the PTO must show adequate support for its findings on the scope of the field of endeavor in the application's written description and claims, including the structure and function of the invention.

In re Bigio (No. 03-1358; August 24, 2004). It is submitted that the rejection does not reference the application to support the findings on the scope of the field of endeavor and it appears that the Examiner's assessment was a wholly subjective call.

This test does not make the assessment of the field of endeavor a wholly subjective call for the examiner. The examiner and the Board must have a basis in the application and its claimed invention for limiting or expanding the scope of the field of endeavor. In that vein, this court has previously "reminded . . . the PTO that it is necessary to consider 'the reality of the circumstances' – in other words, common sense – in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992) (quoting *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979)) (emphasis added). Accordingly, the

examiner and the Board must consider the "circumstances" of the application – the full disclosure – and weigh those circumstances from the vantage point of the common sense likely to be exerted by one of ordinary skill in the art in assessing the scope of the endeavor. Those factual determinations are neither unbridled nor wholly subjective. Instead this test rests on an assessment of the nature of the application and claimed invention in addition to the level of ordinary skill in the art.

In re Bigio (No. 03-1358; August 24, 2004). Based upon the explanations of the invention's subject matter in the patent application and the claimed invention and considering the reality of the circumstances, one of ordinary skill would not reasonably be expected to look for a solution to the problem facing the inventors (increasing the hydrophilicity of a surface of an analytical test element) by turning to the McGannon reference.

McGannon, discloses the making, shaping and treating of steel. The reality of the circumstances is that the making, shaping, and treating of steel is a macro-scaled operation involving hot, molten metals. In that regard, the Examiner's attention is directed to the temperatures given in the figure legends of McGannon (fig. 12-109, 1570°C; fig. 12-110, 1400°C; fig. 12-111, 1300-1600°C; fig. 12-112, 1500°C, fig. 12-113 silicate melts, and fig. 12-114 liquid iron). The reality of the circumstances is further that analytical test elements, which are the subject of the claimed invention, would be annihilated at such temperatures. As such, common sense would not lead the inventors to the field of steel manufacturing to look for a solution to a problem found with analytical test elements.

There is simply nothing in the specification as filed, the claims as amended, or the reality of the circumstances that would lead one of ordinary skill in the art of test elements in which a sample liquid is transported from a sample application site to a determination site to expect to look for a solution to the problem of increasing the hydrophilicity of a surface of said test element in a reference dealing with the making, shaping, and treating of steel, let alone in Figures addressing surface tension of molten materials at (1300-1600°C). Accordingly, when the circumstances of the application are weighed from the vantage point of the common sense likely to be exerted by one of ordinary skill in the art of analytical test elements in assessing the scope of the endeavor,

it is submitted that the field of endeavor would not be such so as to include molten materials involved with the making and shaping of steel. As such, it is submitted that McGannon is not the same field of endeavor as the methods recited independently in claims 3 and 4 of the present application.

Not only is it submitted that McGannon is not within the field of the inventor's endeavor, but it is further submitted that it is not reasonably pertinent to the particular problem with which the inventors were involved. The problem with which the inventors were involved is specifically set forth at pages 2-4 of the specification. In summary, it is the elimination of disadvantages found in different processes (corona plasma treatment, plasma chemical vapour deposition, the covalent binding of hydrophilic polymers with a photoreactive capability onto a plastic surface described for example in US 4,973,493, the application of layers containing wetting agents onto a plastic surface, or coating of inorganic-organic nanocomposites by means of sol-gel technology on the surfaces to be modified), which have the aim of hydrophilically modifying surfaces, such as plastic surfaces that are used especially in medical diagnostics or environmental analysis. See, pages 2-4 of the specification. The McGannon reference dealing with the making, shaping and treating of steel has nothing whatsoever to do with any of the above processes, and as such cannot be reasonably pertinent to the problem of increasing the hydrophilicity of a surface of said test element. Accordingly, McGannon is not analogous to the claimed invention, and thus does not qualify as prior art for an obviousness determination.

Since Saruwatari et al, Streel, Clough, and AN 115:237352 do not set forth to increase the surface tension of an object by the oxide coating and the coating substrate is an analytical test element it is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a).

For the record, however, it is submitted that Saruwatari et al, Streel, Clough, and AN 115:237352 are not believed to be analogous to the claimed invention, and should not qualify as prior art for an obviousness determination. This is because Saruwatari et al, Streel, Clough, and AN 115:237352, either alone or in combination with one another are not reasonably pertinent to the particular problem with which the inventors were involved.

Saruwatari et al. discloses an aluminum conductor that is roughened and a hydrophilic film formed on the roughened surface (see the abstract). Streel discloses a process for treating a coating of aluminum deposited on a metal support (Col. 1 lines 32-34); Clough discloses a tin coated product to provide a laminated thread with resistance to alkaline dyes (Col. 3 lines 12-16); and AN 115:237352 discloses an oxide coating on aluminum and magnesium that eliminates the need for chromate or other chem. conversion coating processes. None of these references relate to or are pertinent to the problems addressed by the claimed invention and discussed above with reference to McGannon. As such, they are not analogous to the claimed invention, and thus do not qualify as prior art for an obviousness determination.

Accordingly, it is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Entry of the amendments leading to reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

The claims are believed to be in condition for allowance, and allowance of the application is respectfully requested. It is requested that if necessary, this paper be considered a Petition for Extension of time sufficient to effect a timely response, and that all fees due be charged to Deposit Account Number 50-0877 with reference to (RDID 0041 US).

Respectfully submitted,
The Law Office of Jill L. Woodburn, L.L.C.

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(Date)

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